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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/591,632

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Susan Lindquist

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2820

7590

02/07/2005

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EXAMINER

TURNER, SHARON L

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/591,632

Applicant(s)

LINDQUIST ET AL.

Examiner

Sharon L. Turner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 65, 67, 81, 101-110, 116-119, 121-135 and 137-149 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 65, 67, 81, 101-110, 116-119, 121-135, 137-149 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **Response to Amendment**

1. The Examiner of U.S. Patent Application No. 09/591,632 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1647.
2. The amendment filed 7-19-04 has been entered into the record and has been fully considered.
3. Claims 65, 67, 81, 101-110, 116-119, 121-135, 137-149 are pending in new terms, in particular as newly drawn to distinct fibers, isolated filamentous polymers, polypeptides comprising substitutions as noted for example in amended and newly presented claims 121-133 and 144-145, and fibrous polymers.
4. In the previous office action of 1-13-04 Applicants were reminded, "that the claims are under examination only to the extent that they read on the elected invention, i.e. polypeptides having a reactive SCHAG amino acid sequence, comprising SEQ ID NO: 2 or a fragment thereof, a modified cysteine residue, and a metal atom substituent." However, the Examiner appears to have inadvertently included claims to subject matter other than that elected. The newly amended claims 144-145, and 121-133 appear drawn to the previously elected subject matter. However, claims 65, 67, 81, 101-110, 116-119, 134-135, 137-143, 146-149 are distinct and separable as the claims are drawn to fibers, filamentous polymers, purified fibers, polypeptides, polymers, fibrous polymers and purified fibers with different limitations as claimed. Accordingly, restriction is required and the following restriction requirement is imposed as set forth below.

**Election/Restrictions**

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 65, 119, 141 and 142 in part drawn respectively to a fiber as claimed, classified for example in class 526, subclass 199.

II. Claim 67, 143 in part drawn to an isolated filamentous polymer as claimed, classified for example in class 527, subclass 101.

III. Claim 81 in part drawn to a purified fiber as claimed, classified for example in class 424, subclass 1.29.

IV. Claim 101-110, 146-147 in part drawn to a purified fiber as claimed, classified for example in class 930, subclass 25.

V. Claims 116-118 drawn to a fiber as claimed comprising substitutions, classified for example in class 424, subclass 9.322.

VI. Claims 121-123, 139 and 144 in part drawn to a polypeptide, classified for example in class 530, subclass 300.

VII. Claims 124-126, and 132 in part drawn to a polypeptide as claimed, classified for example in class 530, subclass 350.

VIII. Claims 127-131, 133 in part drawn to a polypeptide as claimed, classified for example in class 530, subclass 350.

IX. Claims 134-135, 137-138 in part drawn to a polymer, classified for example in class 526, subclass 199.

X. Claims 139-140, 145 in part drawn to a fibrous polymer as claimed, classified for example in class 526, subclass 199.

XI. Claims 148-149 in part drawn to a purified fiber as claimed, classified for example in class 527, subclass 101.

6. The inventions are distinct, each from the other because of the following reasons:

7. Inventions I-XI are related as products. The products are distinct each from the other as the products are comprised of divergent structure, exhibit different effects and function, for example in higher order structure and amino acid composition comprising polypeptide, fibers, purified preparations, fibrous preparations or filamentous preparations and thus comprise different search and analysis of the prior art.

8. Inventions I-XI are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinguished in their unique polypeptide sequence structure and higher order fiber, fibrous, or filamentous polymer structure. Each of the distinguished aggregates exhibit different functions and effects, for example beta- amyloid fibrils are denoted in Alzheimer's disease whereas prions are denoted in scrapie disease. Further, the higher order structure distinguishes different use or effect. For example, beta sheet structure amyloid is pathogenic whereas alpha helix structure amyloid is not. Thus the polypeptides and different aggregate formations differentially effect biological processes and therefore are capable of different use and or function and are therefore separable. Further the substituted amino acid compositions may differ in structure, function and effects, for example for use in detection or the generation of antibodies for labeling.

9. Furthermore, in addition to the election of one of the above VIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

All claims are in part directed to a "SCHAG amino acid sequence" as generically claimed, inclusive of the description at pp. 6-8 of the specification denoting peptides of variable amino acid sequences and lengths. For each group Applicants are required to delineate the SCHAG sequence to which the search will be limited. At least the following different sequences are denoted; SEQ ID NO's: 2, 4, 17, 19, 21-36, 46-47 and 50 and yeast or other prion aggregation domains. In particular the specific SCHAG sequence is required to be delineated along with the specific amino acids of the sequence and where in generic form any substitution should be deemed to occur.

10. Restriction is deemed to be proper because the products indicated constitute patentably distinct inventions for the following reasons. Each of the polypeptides has a unique structural feature which requires a unique search of the prior art. The inventions indicated further differ in higher order structure and function as they are composed of divergent aggregate formations which Applicants proposed as patentably distinguishing, i.e., fibers, fibrous aggregates and filamentous aggregates which are differentially able to bind and/or mediate biological functions. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

12. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, **Applicant is required to elect a single group from designated groups I-XI and a single molecular embodiment for the SCHAG amino acid sequence to which the claims will be restricted, even though the requirement is traversed.** Applicant is advised that neither election is a species election requirement; rather each is a restriction requirement. The subject matter for examination will be restricted to the extent of the subject matter elected.

**Applicant is advised that a reply to this requirement must include an identification of the sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is

considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant may be entitled to consideration of claims to additional groups which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected groups.

Should applicant traverse on the ground that the groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.



Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.



Sharon L. Turner, Ph.D.  
February 1, 2005

**SHARON L. TURNER, PH.D.**  
**PATENT EXAMINER**